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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,042	04/21/2004	Trevor Barrowcliffe	674583-2001	7419

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/829,042	BARROWCLIFFE, TREVOR	
	Examiner	Art Unit	
	Agnes B Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to a composition comprising FIX and FVIII together for simultaneous use in the treatment of haemophilia A or B; and a method of manufacture of a composition using FIX and FVIII together, classified in class 50, subclass 383, and class 50, subclass 384 respectively, for example.

Claims 13-15, drawn to a method for potentiating FVIII, where FVIII and FIX are used together in a composition, classified in class 50, subclass 384, for example.

II. Claims 1-3, drawn to a composition comprising FIX and a separate composition comprising FVIII for separate use in the treatment of haemphilia A or B, classified in class 50, subclass 383, and class 50, subclass 384 respectively, for example.

III. Claims 9-12, drawn to a method of treatment of a heameophilia A or B using composition comprising FIX and FVIII together, classified in class 50, subclass 383, and class 50 subclass 384, respectively, for example.

IV. Claims 16 and 17, drawn to a method for reducing the immunogenicity of FVIII by administering FIX and FVIII together as one composition, classified in class 50, subclass 384.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and distinct in that Group I is directed to a composition comprising FIX and FVIII together for simultaneous use in the treatment of haemophilia A or B, whereas Group II is directed to a composition where FIX and FVIII are used separately in the treatment of haemphilia A or B. Thus, Group I and Group II are separate inventions since they consist of two different and distinct chemical compositions for the treatment of haemphilia A or B.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention III, the method of treatment of haemophilia A or B, can be performed using other compositions, for example other known blood coagulation factors or proteins, which are different from FIX and FVIII. Moreover, composition of Invention I can be used in other methods of treatment of haemphilia A or B.

Furthermore, Inventions II and III are distinct because Invention II uses separate compositions of FIX and FVIII for separate use in the treatment of haemphilia A or B. On the other hand, Invention III is a method of treatment of a haemophilia A or B, where there is only one composition used in the treatment of haemophilia A or B, which comprises FIX and FVIII together.

Moreover, the method of treatment of Invention III can be performed using other compositions, which are distinct and different from Invention II, such as other factors known as blood coagulation proteins. Also, composition of Invention II can be used in other methods of treatment of haemaphilia A or B.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of Invention IV reduces immunogenicity of FVIII by using FIX and FVIII together, however at the same time the method can be performed by using other known in the art coagulation factors or proteins.

Inventions II and IV are independent inventions, and thus are subject to restriction. Inventions are independent if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case, Inventions II and IV are different because they are not disclosed as capable of use together. Here, Invention IV is a method of reducing immunogenicity of FVIII where FIX and FVIII are used together in one composition. On the other hand, Invention II uses two separate FIX compositions and separate FVII composition, thus it is clear, that Invention II and IV have different method of operation, different functions and thus different effects.

Inventions III and IV are independent inventions, and thus are subject to restriction. The inventions are independent processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case, Invention III is a method of treating heamophilia A or B where a subject does not present anti-FVIII antibodies. On the other hand, Invention IV is a method for reducing the immunogenicity of FVIII in a subject who possesses FVIII. Therefore, Invention II and IV are patently distinctive.

Therefore, the aforementioned Groups of Inventions are distinct for the reasons given above, and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and additionally a search for one group does not require a search for another group. Moreover, a search and examination of all inventions in one patent application would result in an undue burden. Thus, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, which ever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37CFR1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai*, *In re Brouwer* and 34 U.S.C. 103(b)," 1164 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner before the patent issue withdraws the restriction requirement. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If it attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-27-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

JON WEBER
SUPERVISORY PATENT EXAMINER